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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,694	01/24/2002	Stephane Gobron	CL/V-31975A	1035

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PATENT DEPARTMENT  
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EXAMINER
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MAYES, MELVIN C

ART UNIT	PAPER NUMBER
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1734

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/056,694

**Applicant(s)**

GOBRON ET AL.

**Examiner**

Melvin Curtis Mayes

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-34 and 48-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-34 and 48-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/23/06</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

(1)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(2)

Claims 1, 3, 9 and 48-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 and Martin et al. 5,649,410.

EP 0 131 227 (EP '227) discloses a method of making a contact lens comprising: extruding a film of thermoplastic processable material; punching a blank from the film; molding the blank between two molding dies (first and second mold parts) at a temperature higher than the glass transition point of the thermoplastic material by 20-80°C but lower than the melt flow temperature thereof (thus between 120°C below glass transition temperature and the degradation temperature) at a pressure of 10-100 kg/cm<sup>2</sup> to form the contact lens. EP discloses that the film can have a thickness of 0.1-1 mm, discloses punching a blank of diameter of 9 mm, discloses hydrating the contact lens and discloses that the thermoplastic material can be selected from: cellulose ester, homopolymer or copolymer of methacrylate ester, acrylate ester, styrene, acrylonitrile and vinyl chloride; polycarbonate, polyamide or a polymer blend of these (which includes polymers which are hydrophilic, form a hydrogel when hydrated or contain latent crosslinking groups) (see also corresponding document JP 60-49906). EP '227 does not specifically disclose providing the molding dies (mold parts) with clearance such that gas

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escapes from the mold cavity but none of the thermoplastic material (polymer) escapes or disclose packaging the contact lens.

Yang et al. 6,042,754 teaches that in molding ophthalmic lenses using upper and lower dies, the die set can be provided such that only air is vented out and all of the material is kept inside of the die set (col. 11, lines 49-52).

Martin et al. teach that the manufacturing assembly line for contact lenses includes molding, hydrating and inserting into packaging elements (col. 2, lines 5-67).

It would have been obvious to one of ordinary skill in the art to have modified the method of EP '277 for making a contact lens by providing the two molding dies with clearance such that gas escapes from the mold cavity but none of the thermoplastic material (polymer) escapes, as taught by Yang et al. for making an ophthalmic lens using a pair of dies.

It would have been obvious to one of ordinary skill in the art to further modified the method of EP '227 by packaging the hydrated contact lens as Martin et al. teach that the manufacturing assembly line for contact lenses includes molding, hydrating and inserting into packaging elements.

Providing the blank with a length (L) to diameter (D) ratio  $L/D$  in the range between 0.1 and 10.0 would have been obvious to one of ordinary skill in the art, as EP '277 discloses providing the blank with a thickness (i.e. length) of 0.1-1 mm and diameter of 9 mm, thus length/diameter ratio of 0.011-0.11, which overlaps the claimed  $L/D$  ratio range of 0.1-10.

(3)

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 and Martin et al. 5,649,410 as applied to claim 1, and further in view of either Ruhlin 5,100,590 or Lee 4,619,793.

Ruhlin teaches that in addition to cutting a blank for an ophthalmic lens from a plate for molding, a blank can be cut from a rod (col. 2, lines 34-36).

Lee teaches that a lens blank for making a contact lens can be cut from a suitable rod, punched or stamped from a sheet or cast from molds (col. 9, lines 24-29).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by cutting the blank from an extruded rod (wire) instead of from an extruded film, as taught by either Ruhlin or Lee, as alternatives for providing a blank for making an ophthalmic or contact lens. Punching a blank from a film or cutting a blank from a wire to form a blank of the dimensions as suggested by EO '277 would have been obvious to one of ordinary skill in the art as alternatives for providing a blank for forming a contact lens.

(4)

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754, Martin et al. 5,649,410 and either Ruhlin 5,100,590 or Lee 4,619,793 as applied to claim 4, and further in view of Ingram 5,456,587.

Ingram teaches that a plastic pellet delivery system for automatic placement of a pellet in a mold for molding is provided by moving a knife to engage the extrudate from the nozzle of the extruder, cutting a pellet from the extrudate, moving the knife toward the mold and using plungers to deflect the pellet toward the mold (col. 1-3).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing the blank from an extruded rod (wire) to the mold by providing a knife which cuts the blank from the extrudate from the extruder, moving the knife to the mold and using plungers (ejector pins) to deflect the blank to the mold, as taught by Ingram as used to deliver a plastic pellet from an extruder to a mold.

(5)

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 and Martin et al. 5,649,410 as applied to claim 1, and further in view of Yamanaka et al. 6,099,765.

Yamanaka et al. teach that funnel-shaped holding pad formed of silicon rubber and connected to a vacuum source for holding optical material to the holding pad is used to hold optical material when moving it into and away from the mold apparatus (col. 4, lines 17-25).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by using a silicon rubber pad and vacuum to separate the contact lens from the dies, as taught by Yamanaka et al., as known for use to hold optical material when moving it away from the mold apparatus.

(6)

Claims 10, 12-22, 24, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754.

EP 0 131 227 (EP '227) discloses a method of making a contact lens comprising: extruding a film (ribbon) of thermoplastic processable material (thus at a temperature between 50°C below the glass transition temperature and 50°C above the degradation temperature);

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punching a blank from the film; molding the blank between two molding dies (first and second mold parts) at a temperature higher than the glass transition point of the thermoplastic material by 20-80°C but lower than the melt flow temperature thereof (thus between 120°C below glass transition temperature and the degradation temperature) at a pressure of 10-100 kg/cm<sup>2</sup> for 5-120 minutes to form the contact lens. EP discloses that the film can have a thickness of 0.1-1 mm (thus between 50 microns and 5 mm), discloses hydrating the contact lens and discloses that the thermoplastic material can be selected from: cellulose ester, homopolymer or copolymer of methacrylate ester, acrylate ester, styrene, acrylonitrile and vinyl chloride; polycarbonate, polyamide or a polymer blend of these (which includes polymers which are hydrophilic, form a hydrogel when hydrated or contain latent crosslinking groups) (see also corresponding document JP 60-49906). EP '227 does not specifically disclose providing the molding dies (mold parts) with clearance such that gas escapes from the mold cavity but none of the thermoplastic material (polymer) escapes.

Yang et al. 6,042,754 teaches that in molding ophthalmic lenses using upper and lower dies, the die set can be provided such that only air is vented out and all of the material is kept inside of the die set (col. 11, lines 49-52).

It would have been obvious to one of ordinary skill in the art to have modified the method of EP '277 for making a contact lens by providing the two dies with clearance such that gas escapes from the mold cavity but none of the thermoplastic material (polymer) escapes, as taught by Yang et al. for making an ophthalmic lens using a pair of dies.

Punching the blank from the film by a punch and die wherein a molding die is placed below the punch and die such that the punched blank is clamped between the punch and die and

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drops through the die into the molding die would have been obvious to one of ordinary skill in the art to allow punching and molding of the thin and fragile blank without handling between punching and molding steps.

Using an extruder having a closed-loop pressure feedback control system coupled to the pump, as claimed in Claim 16, would have been obvious to one of ordinary skill in the art as a suitable extruder that can be used to extrude the polymer.

(7)

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 as applied to claim 22, and further in view of either Yang et al. 6,015,512 or Lefebvre 5,458,820.

Yang et al. teach that mold dies for making thermoplastic optical articles are cleaned in distilled water and dried before use for molding (col. 9, lines 5-6).

Lefebvre teaches that before molding a thermoplastic ophthalmic lens, the molding surfaces are preferably wiped with acetone to degrease them and render them chemically clean (col. 7, lines 1-3).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by cleaning the molding dies after molding, as taught by Yang et al. or Lefebvre, to process the dies for reuse for molding contact lenses.

(8)

Claims 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 as applied to claim 10, and further in view of WO 00/53401 (WO '401) Abstract.



EP '277 discloses molding the contact lens blank for 5-120 minutes to form the contact lens (thus encompassing less than 500 seconds as claimed in Claim 30). EP also discloses that the film can have a thickness of 0.1-1 mm (thus between 0.05 mm and 1.0 mm as claimed in Claim 26).

WO '401 Abstract teaches that in making a contact lens having no air inclusions and clean and thin edge, a three-part mold is used which defines a molding cavity and a drainage and retention volume to accept excess molding compound and pull away the excess during disassembly.

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing the molding dies with a third part so as to form a drainage and retention volume, as taught by WO '401 Abstract, to form a contact lens having no air inclusions and a clean and thin edge. By providing the molding dies with a third part such that excess blank is accepted and pulled away, the mold cavity is provided with a flange mold cavity into which a flange is formed and removed from the contact lens, as claimed.

(9)

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 as applied to claim 10, and further in view of Yamanaka et al. 6,099,765.

Yamanaka et al. teach that funnel-shaped holding pad formed of silicon rubber and connected to a vacuum source for holding optical material to the holding pad is used to hold optical material when moving it into and away from the mold apparatus (col. 4, lines 17-25).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by using a silicon rubber pad and vacuum to separate the lens from the molding dies, as taught by Yamanaka et al., as known for use to hold optical material when moving it away from the mold apparatus.

*Response to Arguments*

(10)

Applicant's arguments filed May 3, 2006 have been fully considered but they are not persuasive.

Applicant argues that EP 0 131 227 discloses a stampable film of the exact weight needed for the final product and does not suggest or have the need to combine with Yang to achieve "having a variable volume between a first volume and a second volume...such that gas escapes from the mold cavity and none of the polymer escapes from the mold cavity" and argues that EP '227 teaches away from the combination.

(11)

Not only does EP '227 disclose that the blank cut from the extruded film has the precise weight of the contact lens to be molded but also discloses molding the contact lens using a pair of stamping dies in molding tools that prevent the escape of the thermoplastic material during molding (see translation, pg. 6-7).

Yang et al. is pertinent to the method of EP '227 because the reference teaches that in molding ophthalmic lenses using upper and lower dies, when an exact amount of the material to form the lens is used, the die set can be provided such that only air is vented out and all of the

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material is kept inside of the die set (col. 11, lines 48-52). The Examiner's position is that it would have been obvious to one of ordinary skill in the art to have modified the method of EP '277 for making a contact lens by providing the two dies with clearance such that gas escapes from the mold cavity but none of the thermoplastic material (polymer) escapes, as taught by Yang et al. for making an ophthalmic lens using a pair of dies and the exact amount of material to form a lens. Clearly the motivation for providing the stamping dies with clearance so that gas escapes but none of the material of the thermoplastic material blank escapes is suggested by EP '227 which discloses that the dies prevent the escape of thermoplastic material during molding and Yang which teaches that when not allowing the material to escape, only air is allowed to vent out, thus suggesting that there must be clearance only large enough to allow for escape of gas when using an exact amount of the thermoplastic material for molding a lens.

### ***Conclusion***

(12)

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

(13)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melvin Curtis Mayes whose telephone number is 571-272-1234. The examiner can normally be reached on Mon-Fri 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on 571-272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Melvin Curtis Mayes  
Primary Examiner  
Art Unit 1734

MCM  
August 14, 2006